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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,830	02/24/2004	Dganit Bar	66401-AA/JPW/DNS	5316
John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER MARSCHER, ARDIN H	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 07/10/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/786,830

**Applicant(s)**

BAR ET AL.

**Examiner**

ARDIN MARSCHEL

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 14-31 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Applicants' Remarks, filed 11/5/07, is hereby acknowledged and have been persuasive that the election requirement, mailed 7/5/07, should be reconsidered. In response, the election requirement, mailed 7/5/07, is hereby VACATED, and replaced by the following set forth below. Due to the newly applied election requirement herein applied, the election, filed 11/5/07, is deemed moot.

### ***Election/Restrictions***

#### **FIRST SPECIE ELECTION REQUIREMENT OF THREE:**

This application contains claims directed to the following patentably distinct species

Species of "candidate spermidine synthase inhibitor" summarized as follows:

A) specific candidate spermidine synthase inhibitors listed instant claim 28 (functional homologs and analogs, however, are deemed obvious variants of inhibitors as specifically listed in instant claim 28)

B) a "generic non-named or specifically disclosed candidate spermidine synthase inhibitor" compound not listed in instant claim 28 but within the scope of instant claim 1, for example, which broadly is inclusive of whatever other candidate spermidine synthase inhibitors that may be tested.

Applicants are cautioned that election of any "specific" candidate spermidine synthase inhibitor that has not been specifically disclosed as filed may be determined to be New Matter.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. Specifically, different candidate spermidine synthase inhibitors with different chemical structures are generally well known to interact with an enzyme such as spermidine synthase with different binding characteristics, different affinities, and different competitive characteristics, for example. Thus, the above species are distinct from each other. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species selected from the listing in A) above, or, the practice of a generic non-named or instantly disclosed inhibitor as summarized in B) above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14-31 are generic to the above listed species.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

#### **SECOND SPECIE ELECTION REQUIREMENT OF THREE:**

This application contains claims directed to the following patentably distinct species

Species of "test system for evaluating the effect of a candidate spermidine synthase inhibitor compared to a control" as summarized as follows:

C) a specific test system comprising DNA encoding spermidine synthase as set forth in instant claim 15

D) a mixture specifically comprising spermidine synthase as in instant claim 29

E) a "generic non-named or specifically disclosed test system not listed as summarized in the above species but within the scope of instant claim 1, for example, which broadly is inclusive of whatever other test system may be utilized.

IF specie C) is elected above, then the following further specie election requirement is hereby applied:

A specie election from the following:

C-1) an in-vitro transfected cell culture as in instant claim 16

C-2) an ex-vivo bone culture as in instant claim 18

C-2) an in-vivo test system comprising an animal model

Applicants are cautioned that election of any "specific" test system that has not been specifically disclosed as filed may be determined to be New Matter.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. Each test system needs to be analyzed differently due to measurement methodology that will vary greatly based on what test system is being utilized. For example, a test system with DNA encoding spermidine synthase may be inhibited at the functionally distinct sites of transcription, translation, or direct enzyme interaction; versus a mixture of enzyme(s) as in instant

claim 29. Also, the test systems that utilize cell cultures of various types will involve very different analysis determination methodology in order to focus on spermidine synthase effects per se due the generally well known differences and complexities of such cultures and animal models, in particular. Thus, the above species are distinct from each other. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species selected from the listing in C) or D) above, or, a generic non-named or instantly disclosed test system summarized in E) above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14 and 28 are generic to the above listed species.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### **THIRD SPECIE ELECTION REQUIREMENT OF THREE:**

This application contains claims directed to the following patentably distinct species



Species of "effect being evaluated to determine identification of an inhibitor of spermidine biosynthesis" as summarized as follows:

F) "Non-end point indication" of an effect (an embodiment of instant claim 14 which is deemed to be broader than instant dependent claim 15 which is limited to determining the effect of the test candidate inhibitor via "end point indication".

G) "End point indication" of an effect as required in instant claim 15, for example IF specie G) is elected above, then the following further specie election requirement is hereby applied:

- G-1) chondrocyte proliferation (See, for example, claims 14 and 15.)
- G-2) chondrocyte final differentiation (See, for example, claims 14 and 15.)
- G-3) angiogenesis (See, for example, claims 14 and 15.)
- G-4) osteoclastogenesis (See, for example, claims 14 and 15)
- G-5) development of arthritis (See, for example, claim 21.) \*\*
- G-6) inhibition of spermidine synthase in a mixture as in instant claim 29 \*\*

\*\* Applicants are cautioned that the election of the above end point determination must reasonably correspond to the test system elected in the above "Second" specie election such that the election of an end point indication may be determined to be New Matter if such correspondence is not set forth in the elections of applicants. For example, the above species G-5) and G-6) reasonably correspond to specific test system practice.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. It is well known that

Art Unit: 1614

cellular vs. enzyme mixtures, for example, are very different systems as to what constitutes an end point versus general non-end point inhibition. Inhibition generally is inclusive of enzyme binding or kinetics determinations which are not end points but determinations with effects that usually are graphically shown by varying graphical slopes and parameters in such evaluations. Also, the end point determinations of effect as listed in the above specie options are utilized within well known complex cellular or animal model systems whose effects are generally complex and difficult to separate so as to isolate the effect to a specific systems such as in this case spermidine biosynthesis and thus distinct species by different functions and testing methodology required for each determination. Thus, the above species are distinct from each other. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species selected from the listing in F) or G) above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14 and 28 are generic to the above listed species.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### **Inventorship Notice**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1614 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1614

July 5, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614